

*MUR-045-USA-PCT***REMARKS**

Claims 1-4 have been amended to more definitely set for the invention, and obviate the rejections. Support for the amendment of claims 1-4 can be found in the Specification on page 7, line 26, to page 8, line 2, page 8, lines 15-24, page 9, lines 11-22, and Figures 1-4. The present amendment is deemed not to add new matter. Claims 1-6 are in the application.

Reconsideration is respectfully requested of the rejection of Claims 1-3, 5 and 6 under 35 U.S.C. 103(a) as being unpatentable over McAdams, et al. (USP 6,731,987) in view of Sibalis (USP 4,919,648).

The cited McAdams, et al. reference, as illustrated in Fig. 1, teaches an electrode 1 comprised of a substrate layer 4, an electrically conductive layer 5 which conducts electricity for the supply or the collection of an electrical current traversing the electrode, and a consumable electrochemical interface layer. In addition, a dielectric material layer 8 is disposed against the substrate layer 5, and is in contact with the skin of the patient during use. Importantly, the dielectric material layer 8 is formed so as to contain the electrically conductive layer 5, electrically resistant, chemically inert layer 6, electrochemical interface layer 7, and gel 8, and is flanged at the edge to enable bonding to the substrate layer 4.

When comparing the construction of the McAdams, et al. device shown in Fig. 1 to the structure of the electrode device of the present invention as illustrated in Fig. 4, it can be seen that the devices are arranged in an essentially opposite configuration. Namely, the substrate film 20 of the electrode device 10 of the present invention forms a cup portion 110, as now claimed herein in amended claim 1, and the gel 80 is retained within the cup portion 110 by the walls of the recess 60. Then, as illustrated in Fig. 4,

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a cap member 90 is disposed on top of the gel 80, and attached to the outward flange section 110f by heat sealing.

In contrast, the substrate layer 4 of the McAdams, et al. device 1 merely acts as a substrate upon which to lay the consecutive layers. The dielectric material layer 8 contains the gel 3 and electrically conductive layer 5 within same, and is connected at a flange portion thereof with the substrate layer 1. Thus, unlike the electrode device of the present invention, in which the substrate layer is cupped so as to retain the electrically conductive gel, the McAdams, et al. device provides a flat substrate layer, builds multiple layers upon same, and contains the multiple layers within a flanged dielectric layer 8 which is bonded to the flat substrate.

Further, as the Examiner has recognized, the McAdams, et al. device fails to teach or suggest the deformed portion claimed in amended base claim 1 herein. In order to cure this deficiency, the Examiner has cited the secondary Sibalis reference. Sibalis teaches a high tack transdermal drug patch for delivering a drug to a patient via the skin thereof. In particular, as illustrated in Fig. 1 and Fig. 2, Sibalis discloses an applicator 10 comprising an outer cover 12 having a raised portion 14 and a lip 16.

The Examiner has contended that the cover 12 includes a deformed portion identical or equivalent to the deformed portion 70 as illustrated in Fig. 3 and Fig. 4, and as claimed in base claim 1 herein. However, upon close comparison of Fig. 1 and Fig. 2 of Sibalis, with Fig. 3 and Fig. 4 of the present application, it is clear that Sibalis fails to teach the deformed portion claimed herein, consisting of a protrusion formed in the outward flange section 110f and insulating layer 50. In fact, it is believed that neither McAdams, et al. nor Sibalis disclose the claimed deformed portion. Rather, that teaching or suggestion comes only from the present invention, and constitutes an important element or aspect thereof.

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In conventional electrode devices, leakage of the gel from the recess is frequently encountered, as well as deficient seal strength of the cap member to the substrate film. The present inventors unexpectedly discovered that by forming a deformed portion 70 (consisting of a projection) continuously around the outer periphery of the recess 60, excluding the electrode lead 320 of the electrode layer 30, leaking of the gel out of the cup portion 110 via the recess 60 could be achieved.

In particular, comparative tests were conducted comparing the seal strength of the cap member 90 to the insulating layer 50 and outward flange section 110f at 200°C and 220°C of an electrode device having a flange section provided with the protrusion 70, to an electrode device having a flange section not provided with the protrusion 70. The results of these comparative tests are shown in Tables 1 and 2 on page 12 of the Specification. As evidenced by the comparative test data shown therein, it was unexpectedly discovered that the electrode devices having the deformed portion formed in the outward flange section have superior seal strengths as compared to those electrode devices not having a deformed portion formed therein. Further, it was unexpectedly discovered that when the seal strength is large, fluctuation in the seal strength is small.

It was further discovered that warp (wrinkle and sagging) tended to occur in the outward flange section in the electrode devices not having a protrusion 70 formed therein. In contrast, it was found that electrode devices having a protrusion formed in the outward flange section did not experience warping, and consequently the insulating layer and the electrode layer in the step portion were stable, and the likelihood of crack and disconnection was reduced.

In view of the amendments to base claim 1 herein, the lack of disclosure in both the cited McAdams, et al. reference and Sibalís reference of the now claimed deformed

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portion, and the unexpectedly improved effects of the present invention related to the claimed deformed portion, it is believed that the Examiners' cited combination of references fails to render unpatentably obvious the claims as now presented herein. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of claims 1-3, 5 and 6 under 35 U.S.C. 103(a) as being unpatentable over McAdams, et al. (USP 6,731,987) in view of Sibalis (USP 4,919,648), and further in view of Phipps, et al. (USP 5,125,894)

Both McAdams, et al. and Sibalis are discussed above in detail.

The Examiner has inferred that neither McAdams, et al. nor Sibalis clearly teach a recess for containing gel, as is claimed herein. To cure this deficiency, the Examiner has cited Phipps, et al. As shown in Fig. 3, Phipps, et al. discloses an apparatus for controlled environment electrotransport. Specifically, the apparatus includes a housing 106, which does encompass a gel matrix 141, as argued by the Examiner.

However, as discussed above in detail, the electrode device of the present invention includes (a) a substrate film including: (i) a cup portion having a recess, a bottom disposed adjacent one end of the recess, and a periphery disposed adjacent an end of the recess opposite the bottom, said cup portion opened upward; (ii) an outward flange section surrounding the periphery of the cup portion, and disposed in communication therewith, and (iv) a lead section extending from the outward flange section; (b) an electrode layer including: (i) an electrode body arranged on the bottom of the cup portion; and (ii) an electrode lead section extending from the bottom of the cup portion, up the recess, and over the outward flange section of the substrate film; and (c) *a deformed portion formed in the outward flange section, so as to surround the*

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periphery of the cup portion, said deformed portion operable to cause the outward flange section of the substrate film to project or hollow.

Neither McAdams, et al., Sibalis, nor Phipps, et al. teach the deformed portion as claimed herein. Moreover, neither of the cited references teach or suggest that such a deformed portion can prevent leakage of the gel from the cup portion via the recess, or that the deformed portion can provide far superior seal strength between the cap member and the substrate film (which acts to contain the gel). Rather, these teachings or suggestions come only from the present invention, and constitute an important element or aspect of the present invention.

In view of the amendments to claim 1 herein, as well as the deficiencies of the cited combination of references pointed out above, it is believed that the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,

TOWNSEND & BANTA

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I hereby certify that this facsimile transmission, consisting of a 9-page Amendment and 1-page Transmittal, in U.S. patent application serial No. 10/517,535, filed on September 12, 2005, is being facsimile transmitted to the U.S. Patent and Trademark Office (Fax no. 571-273-8300) on January 28, 2008.

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